

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-60. (Canceled)

61. (Previously Presented) An isolated polynucleotide comprising the sequence of SEQ ID NO:808.

62. (Currently Amended) An isolated polynucleotide comprising a sequence having at least 90% identity with the entirety of the sequence of SEQ ID NO:808, wherein the polynucleotide ~~can be used in the detection of lung cancer~~ hybridizes under moderately stringent conditions to a polynucleotide comprising the complement of the sequence of SEQ ID NO:808.

63-65. (Canceled)

66. (Currently Amended) An isolated polynucleotide comprising the complement of a polynucleotide of any one of claims 61, 62 or 69, wherein the polynucleotide ~~can be used in the detection of lung cancer~~ hybridizes under moderately stringent conditions to a polynucleotide comprising the sequence of SEQ ID NO:808.

67. (Previously Presented) An expression vector comprising a polynucleotide according to any one of claims 61, 62 or 69.

68. (Previously Presented) A host cell comprising an expression vector of claim 67.

69. (Previously Presented) An isolated polynucleotide comprising at least 175 contiguous residues of the polynucleotide sequence of SEQ ID NO:808.

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks. Claims 61, 62 and 66-69 are pending and currently under consideration. Claims 62 and 66 have been amended to more specifically recite certain aspects of the invention. Support for these amendments may be found throughout the specification and claims as originally filed, and it is urged that the amendments do not constitute new matter. It should also be noted that the above amendments are not to be construed as acquiescence with regard to the Examiner's rejections and are made without prejudice to prosecution of any subject matter removed or modified by this amendment in a related divisional, continuation or continuation-in-part application.

Entry of Prior Amendment

The Advisory Action mailed October 1, 2002 indicates that the prior amendment submitted September 10, 2002 was entered. However, the status of claim 69, which was newly submitted in the amendment of September 10, 2002, is not indicated in the Advisory Action. Since the amendment was entered, Applicants submit that claim 69 is currently pending and respectfully request consideration of this claim. Applicants note that claim 69 is directed to isolated polynucleotides comprising at least 175 contiguous residues of SEQ ID NO:808. Support for claim 69 is provided in the application as originally filed, *e.g.*, at page 67, lines 6 to 12. Applicants respectfully submit that the subject matter of this claim is encompassed by original claim 4 and, therefore, does not constitute new matter. Applicants further submit that the search performed for the subject matter of original claim 4 would have uncovered all relevant art related to the subject matter of claim 69, so a new search is not required.

Rejection Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 62 and 66-68 stand rejected under 35 U.S.C. § 112, first paragraph, on the alleged basis that the specification does not reasonably provide enablement for the use of polynucleotides having at least 90% identity with SEQ ID NO:808 for the diagnosis of lung cancer.

Applicants respectfully traverse this basis of rejection and submit that the specification is clearly enabling regarding the use of the claimed polynucleotides for the diagnosis of lung cancer, as recognized on page 4, lines 2-3, of the Final Office Action mailed July 19, 2002. However, to expedite prosecution of the instant application, claims 62 and 66 have been amended to remove reference to the use of the claimed polynucleotides in the detection of lung cancer. Instead, the claims now contain the limitation that the claimed polynucleotides hybridize under moderately stringent conditions to a polynucleotide comprising a complement of SEQ ID NO:808 or a sequence of SEQ ID NO:808, respectively. Support for these amendments is provided throughout the specification as originally filed, including, *e.g.*, on page 67, line 24 through page 68, line 3. Applicants note that these amendments are made in light of the telephone interview conducted February 4, 2003 between the Examiner and Applicants' representative, wherein the Examiner provisionally indicated that claims containing this limitation were adequately enabled by the instant specification and that the present amendment would overcome this basis of rejection. In light of these amendments, Applicants respectfully request reconsideration and withdrawal of this basis of rejection.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 62 and 66-68 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter lacking adequate written description in the specification. More specifically, the Action alleges that the genus of nucleotide sequences having at least 90% identity to SEQ ID NO:808 lacks sufficient written description, since the genus is highly variable and the effects of changes in structure are largely unpredictable. Furthermore, the Action contends that the specification does not indicate the common attribute of the claimed polynucleotides that is required for their usefulness in the detection of lung cancer.

Applicants respectfully traverse this basis of rejection and submit that the claimed subject matter is adequately described in the instant specification and, thus, meets the requirements of 35 U.S.C. § 112, first paragraph.

As an initial matter, Applicants submit that the claimed invention is based upon Applicants' discovery that L552S polynucleotides (SEQ ID NO:808) are overexpressed in cancer

and may be used, *e.g.*, in the detection of lung cancer using nucleic acid hybridization-based methods of detecting L552S polynucleotides. Applicants further submit that it is widely known and accepted in the art that such methods, including, *e.g.*, PCR and northern blotting, do not require that the polynucleotide probe has the identical sequence as the polynucleotide being detected. Rather, it is absolutely understood that polynucleotides having significantly less than 100% identity to the polynucleotide being detected can specifically hybridize to and be used to detect a particular polynucleotide. Applicants further submit that the skilled artisan would clearly recognize that sequences having at least 90% identity to SEQ ID NO:808 would, indeed, specifically hybridize to L552S polynucleotides of SEQ ID NO:808 and could be used to detect the overexpression of L552S polynucleotides of SEQ ID NO:808.

Regarding the Action's contention that the specification does not indicate the common attribute of the claimed polynucleotides that is required for their usefulness in the detection of lung cancer, Applicants strongly disagree. As indicated above, Applicants submit that the skilled artisan would recognize that the only necessary common attribute of the claimed polynucleotides is the ability to specifically hybridize to L552S polynucleotides having the sequence set forth in SEQ ID NO:808. Furthermore, Applicants submit that the skilled artisan would recognize that the claimed polynucleotides all possess this attribute. Applicants further submit, contrary to the Action's assertion, that the effect of changes in the sequence, *i.e.*, structure, of polynucleotides of SEQ ID NO:808 is not unpredictable, particularly as related to their ability to specifically bind L552S polynucleotides of SEQ ID NO:808. Indeed, Applicants submit that the skilled artisan would appreciate that such changes would not effect the ability of the claimed polynucleotides to specifically bind to L552S polynucleotides of SEQ ID NO:808 and, therefore, be useful for detecting L552S polynucleotide overexpression and, consequently, diagnosing lung cancer. Finally, Applicants note that the specification explicitly describes the claimed polynucleotide variants as possessing this attribute (*see, e.g.*, page 67, lines 24-26).

In addition, Applicants submit that under the Examination Guidelines set forth by the Patent and Trademark Office, the written description requirement for a claimed genus may be satisfied by the description of a representative number of species or the disclosure of relevant, identifying characteristics, sufficient to show the applicant was in possession of the claimed

genus. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶1, “Written Description” Requirement, 66 Fed. Reg. 1099, at 1106. Applicants note that the Guidelines clearly provide that acceptable identifying characteristics include both sequence and binding affinity. *Id.* at 1110. In fact, the examples provided in the Guidelines of sufficiently detailed, relevant identifying characteristics that provide evidence that applicant was in possession of the claimed invention include, “complete or partial structure....functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of these characteristics.” *Id.* at 1106.

Applicants submit that the instant specification discloses sufficient identifying characteristics for L552S-related polynucleotides with at least 90% identity to the polynucleotide of SEQ ID NO:808, since it provides both a reference sequence, percent identity limitations, and the functional limitation that the claimed sequences specifically bind to a polynucleotide of SEQ ID NO:808. Applicants submit that the identified sequence and binding characteristics of the claimed polynucleotides clearly demonstrate that Applicants were in possession of the claimed genus. Applicants also submit that the characteristic of having at least 90% identity to the sequence of SEQ ID NO:808 is undeniably a partial structure, which is acknowledged in the Guidelines as being a sufficient, relevant identifying characteristic. In addition, Applicants submit that this structural characteristic, particularly when coupled with the functional characteristic of specifically binding to a polynucleotide of SEQ ID NO:808 and in light of the known correlation between sequence and specific binding, clearly establishes that Applicants were in possession of the claimed invention.

Furthermore, Applicants submit that the instant specification, by providing the sequence of SEQ ID NO:808 and requiring that the claimed variants have at least 90% identity to said sequence, effectively describes a representative number of species, so as to satisfy the written description requirement. Applicants further submit that the claimed genus of L552S polynucleotide variants having at least 90% identity to SEQ ID NO:808 includes a limited number of species, which could be readily predicted and identified by the skilled artisan based upon the sequence provided in SEQ ID NO:808. Applicants note that the Guidelines explicitly state that “[a] ‘representative number of species’ means that the species which are adequately

described are representative of the entire genus” and that “there may be situations where one species adequately supports a genus.” *Id.* at 1106. The Guidelines further note that “satisfactory disclosure of a ‘representative number’ depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed” and that “[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.” *Id.* Applicants submit that the skilled artisan would clearly recognize that Applicants were in possession of the claimed genus based upon the disclosure of the polynucleotide sequence of SEQ ID NO:808, particularly in light of the associated percent identity and functional limitations and the clear appreciation in the art that the claimed polynucleotide variants would specifically bind to a polynucleotide of SEQ ID NO:808 and be useful in determining overexpression of L552S polynucleotides of SEQ ID NO:808. Furthermore, and as emphasized in prior communications, Applicants emphatically submit that to accept the Action’s position that Applicants were only in possession of polynucleotides consisting of the single species of SEQ ID NO:808 would inappropriately exclude an entire class of polynucleotides related to SEQ ID NO:808 that the skilled individual would appreciate were in Applicants’ possession at the time of filing.

In light of these remarks, Applicants submit that the instant claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, and respectfully request that this basis of rejection be reconsidered and withdrawn.

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Reply to Advisory Action dated October 1, 2002

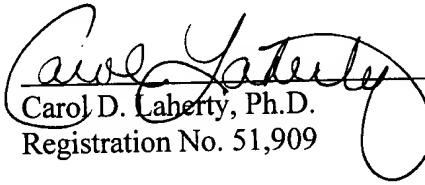
The Commissioner is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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